REMARKS

Claims 1-21 are pending. Claim 6 and withdrawn claims 9-21 have been cancelled without prejudice or disclaimer. New claims 22-25 are introduced. Accordingly, after entry of this Response, claims 1-5, 7, 8 and 22-25 will be pending for consideration.

Information Disclosure Statement

The Examiner has indicated that the reference by Pourahmadi et al., U.S. Patent Application Publication No. 2002/0055167A1, cited in the Supplemental Information Disclosure Statement (SIDS) filed November 4, 2005, was not found.

Applicant respectfully requests that the Examiner consider this reference (copy enclosed) as the previously submitted Form PTO-1449 contained an inadvertent error in the publication number, i.e., it was missing the first zero after the forward slash. Applicant encloses a copy of the Form PTO-1449, which was submitted with the SIDS on November 4, 2005, and respectfully requests that the Examiner indicate consideration of the reference by initialing and dating the form where appropriate.

New Claims

Applicant presents new claims 22-25 for the Examiner's consideration, which claims explicitly recite detection of HIV in a sample fluid. Support for these claims is found in claims 1-7 as originally filed. Accordingly, Applicant submits that no new matter is introduced.

Specification/Claim Objections

The Office action has objected to claim 6 as allegedly being of improper dependent form. Without acquiescing to the objection, Applicant has cancelled claim 6 thereby rendering its objection moot.

Claim Rejections – 35 U.S.C. §112, First Paragraph

The Office action has rejected claim 7 as allegedly failing to comply with 35 U.S.C. §112, first paragraph. In particular, the Office action asserts that the specification fails to provide guidance as to the precise truncated CD4 glycoprotein moiety with which one of ordinary skill in the art could practice the invention.

Applicant respectfully disagrees. Specifically, a person of ordinary skill would be well aware of the interaction between CD4 and the gp120 protein on HIV. This interaction and binding has been characterized and described in the literature, and it is generally known which regions of CD4 are involved in binding to gp120 (see, for example, Wu et al. (1996) *Proc. Natl. Acad. Sci. USA* 93:15030-15035; and Chirmule and Pahwa (1996) *Microbiological Reviews* 60(2):386-406; copies of which are attached behind Tabs A and B, respectively). As well, many soluble forms of CD4 glycoprotein (sCD4) are commercially available, and can be purchased and readily tested for suitability with the instant method. sCD4 is known to bind to HIV *in vitro* and a skilled person would appreciate that such commercially available forms of sCD4 glycoprotein is a truncated CD4 glycoprotein and could be used in the instant methods.

A skilled person would understand, as well, that whether the truncated CD4 glycoprotein used was from recombinant sources or from native sources does not influence the practice of the instant method. In fact, some commercially available sCD4 is recombinantly produced and is capable of binding gp120 (see, for example, the product specification for recombinant human soluble CD4 produced by ProSpec-Tany TechnoGene Ltd., a copy of which is attached behind Tab C).

Furthermore, a skilled person will appreciate that the portion of CD4 used in the instant method is not essential, provided that the truncated CD4 protein used is able to bind to HIV. Since the binding interaction between CD4 and gp120 has been characterized, undue genetic engineering experiments are not required. Rather, a skilled person can readily determine, using known methods in the art including recombinant DNA technology, proteolysis, gel shift assays, immunoassays, and other well developed techniques, whether or not a particular truncated CD4 glycoprotein interacts with and binds to HIV. Such methods would not require undue experimentation, and would be a matter of routine laboratory work.

The Office action has queried whether HIV particles bind non-glycosylated CD4. Claim 7 indicates that it is a truncated CD4 glycoprotein that is used in the instant method.

Applicant therefore respectfully requests reconsideration and withdrawal of the rejection of claim 7 under 35 U.S.C. §112, first paragraph.

The Office action has also rejected claim 8 under 35 U.S.C. §112, first paragraph, on the basis that the specification allegedly fails to provide details regarding the filtering aperture limits required to produce a micro injected molded plastic capable of filtering analyte particles. Applicant draws attention to paragraph [0027] of the instant application, where the specification indicates that exemplary aperture widths for a device that detects HIV can be between 80 and 150 nanometers.

As well, Applicant submits that a skilled person could determine the necessary aperture widths required to detect a particular analyte particle or reagent-analyte particle complex. Common techniques can be used to determine the size of analyte particles or reagent-analyte particle complexes that are desired to be detected, including electron microscopy, dynamic light scattering, X-ray crystallography and NMR techniques, for example. These methods are all known in the art, and determining the particle size of the particular analyte particle or reagent-analyte particle complex would not require undue experimentation.

Once a skilled person had determined the size of the analyte particle and/or reagent-analyte particle complex, a skilled person could readily use nanotechnology and microtechnology fabrication methods, which methods are generally known in the art (see, for example, paragraphs [0020] and [0021] of the instant application), to manufacture a filtering aperture with an appropriate size so as to allow for removal of particles larger than the analyte particle or removal of particles smaller than the reagent-analyte particle complex, as claimed. Such methods would not require undue experimentation given the knowledge in the art regarding determination of particle size and regarding nanotechnology and microtechnology fabrication methods, and the development of an appropriate filtering aperture would not be unpredictable.

Accordingly, Applicant submits that the instant application provides sufficient guidance to a skilled person to manufacture suitable filters and devices so as to practice the claimed methods using micro-injected molded plastic for filtering. Applicant therefore respectfully requests reconsideration and withdrawal of the rejection of claim 8 under 35 U.S.C. §112, first paragraph.

Claim Rejections – 35 U.S.C. §102

The Office action has rejected claims 1-3 and 5 under 35 U.S.C. §102(b) as allegedly being anticipated by Coller et al. (U.S. Patent No. 3,872,225). In particular, the Office action asserts that Coller et al. describes isolation of the Australia antigen (likened by the Office action to the claimed analyte) from human blood plasma by passing fluid containing the Australia antigen over a gel filtration column to separate the antigen from particles that are larger than the antigen. Applicant respectfully traverses this rejection for at least the following reasons.

To sustain a rejection under 35 U.S.C. §102, the Office action must establish

> "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Coller et al. in fact describes separation of the Australia antigen from molecules that are smaller than the antigen. Particularly, at column 4, lines 39-45, Coller et al. states:

> "Five ml aliquots of the enzyme treated suspension above were subjected to gel filtration through a column of preferably Sephadex G-200 produced by Pharmacia, Uppsala, Sweden. This column retards the smaller units but allows the larger Au to come through quickly. Salts and inorganic materials are also retarded. The Au(1) comes through in the first peak."

Thus, Coller et al. explicitly states that the gel filtration column retards smaller units but allows the larger Australia antigen to come through quickly, and that the Australia antigen is eluted in the first peak from the column.

Applicant points out that gel filtration columns work such that particles larger than the pore size of the column matrix pass through quickly and smaller particles are retained in the larger column bed volume. The fact that the Australia antigen was one of the first species to elute from the column indicates that it is not being retained in the column bed and is therefore larger than the pore size of the column matrix. Molecules that are larger than the Australia antigen would co-elute in the first peak along with the Australia antigen. In fact, any molecule or particle that is larger than the pore size of the column matrix would be found in the first peak, including the Australia antigen, and only particles smaller than the pore size of the column matrix would be effectively removed from the sample. Thus, only molecules smaller than the

pore size of the column matrix are being removed from the solution containing the Australia antigen.

Thus, Coller et al. describes removal of particles smaller than the pore size of Sephadex G-200 gel from a sample fluid containing the analyte, namely the Australia antigen, and does not describe removal of particles larger than the analyte.

In contrast, claim 1 of the instant application requires that the method involves "filtering a sample of said fluid to remove particles in said sample larger than said analyte particle". This would result in a sample fluid containing the analyte particles along with species smaller than the analyte particle, as opposed to a sample fluid containing analyte particles as well as species larger than the analyte particle, as is the case in Coller et al.

Because Coller et al. does not describe a two-step isolation process in which an antigen is first separated from particles that are larger than it followed by separation from particles that are smaller than it, Coller et al. does not anticipate claim 1.

Claims 2, 3 and 5 each depend directly or indirectly from claim 1. Therefore Coller et al. similarly does not describe the methods as claimed in these claims.

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 1-3 and 5 under 35 U.S.C. §102(b).

Claim Rejection – 35 U.S.C. §103

The Office action has rejected claims 4, 6 and 7 under 35 U.S.C. §103(a) as allegedly being unpatentable over Coller et al. in view of Motomura et al. (U.S. Patent No. 5,667,684) and further in view of King et al. (U.S. Patent Application Publication No. 2001/008760).

Further to the reasons given above, Coller et al. does not describe, teach or suggest a method in which analyte particles are first separated from particles larger than the analyte particle, followed by eventual filtration to remove particles smaller than a reagent-analyte particle complex. Motomura et al. and King et al. do not cure this deficiency, i.e., each does not provide additional teachings to suggest that the gel filtration step in Coller et al. should be

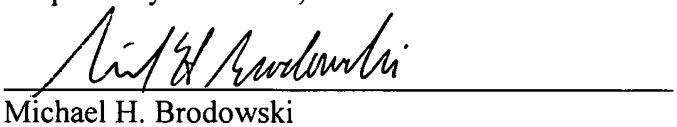
amended to separate an analyte particle from molecules or particles larger than the analyte particle, and therefore do not combine with Coller et al. to render the instant method as obvious.

Applicant therefore respectfully requests reconsideration and withdrawal of the rejection of claims 4, 6 and 7 under 35 U.S.C. §103.

CONCLUSION

In view of the foregoing, it is believed that this application is in condition for allowance. Accordingly, Applicant respectfully requests reconsideration and allowance of this application.

Respectfully submitted,



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